[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

**National Institutes of Health** 

Prospective Grant of Exclusive License: Treatment of Acute and Chronic Neurological

Injuries Involving Axonal Regeneration

**AGENCY:** National Institutes of Health, HHS

**ACTION:** Notice

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404,

that the National Institutes of Health, Department of Health and Human Services, is

contemplating the grant of an exclusive patent license to practice the following inventions

embodied in the following patent applications:

HHS Ref. No.: E-214-2012/0

Titled: "Compositions and Methods for the Treatment of Central Nervous System

Injury"

1. US Provisional Patent Application No.: 61/705,555

HHS Ref. No.: E-214-2012/0-US-01

Filing Date: September 25, 2012

2. PCT Patent Application No.: PCT/US2013/061693

HHS Ref. No.: E-214-2012/0-PCT-02 Filing Date: September 25, 2013

3. Australian Patent Application No.: 2013-32367

HHS Ref No.: E-214-2012/0-AU-03 Filing Date: September 25, 2013

4. European Patent Application No.: 13771750

HHS Ref. No.: E-214-2012/0-EP-04 Filing Date: September 25, 2013

5. U.S. Patent Application No.: 14/430,850

HHS Ref. No.: E-214-2012/0-US-06 Filing Date: September 25, 2013

to BioAxone Biosciences Incorporated ("BioAxone"), a company incorporated under the laws of the State of Delaware having an office in at least Cambridge, Massachusetts, U.S.A. The patent rights in these inventions have been assigned to the United States of

America. BioAxone is seeking all worldwide territories for this license. The field of use may be limited to "Treatment of human acute and chronic neurological injuries involving axonal regeneration, as monotherapy or in combination with other therapeutic drugs or medical devices".

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [INSERT DATE 30DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

**ADDRESSES:** Requests for copies of the patent application, patents, inquiries, comments, and other materials relating to the contemplated exclusive license should be

directed to: Cristina Thalhammer-Reyero, Ph.D., M.B.A., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4507; Facsimile: (301) 402-0220; E-mail: <a href="mailto:thalhamc@mail.nih.gov">thalhamc@mail.nih.gov</a>. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications or patents that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

## **SUPPLEMENTARY INFORMATION:**

This technology, and its corresponding patent applications, is directed to methods of treating or preventing spinal cord injury or a glial scar by administering an agent that reduces the amount or activity of a 4-sulfacted GalNAc in a chondroitin glycosaminoglycan chain, wherein said agent includes human enzyme, arylsulfatase B (ARSB). This technology, and its corresponding patent applications, is also directed to methods of increasing neuron growth, proliferation, or migration by administering an agent that reduces the amount or activity of a 4-sulfacted GalNAc in a chondroitin glycosaminoglycan chain, wherein said agent includes ARSB. This technology may be useful as a means to treat paralysis and motor defects induced by spinal cord injury, such as by promoting axonal regrowth.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the NIH receives written evidence and argument that establishes that

4

the grant of the license would not be consistent with the requirements of 35 U.S.C. 209

and 37 CFR Part 404.

Properly filed competing applications for a license in response to this notice will

be treated as objections to the contemplated license. Comments and objections submitted

in response to this notice will not be made available for public inspection and, to the

extent permitted by law, will not be released under the Freedom of Information Act, 5

U.S.C. 552.

Dated: June 30, 2015.

Richard U. Rodriguez,

Acting Director,

Office of Technology Transfer,

National Institutes of Health.

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